Spring 1986

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Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

James E. Peterson

Keywords

orthokeratology, myopia reduction, corneal modification

Subject Categories

Optometry

CORNEAL MODIFICATION THROUGH ORTHOKERATOLOGY

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SUBMITTED TO THE FACULTY OF

PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY

FOR PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

DOCTOR OF OPTOMETRY DEGREE

SPRING 1986

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Abstract

This paper contains a review of the literature covering history, techniques, patient selection, mode of orthokeratology, current studies of the procedure, and complication of orthokeratology. Orthokeratology is the programmed application of contact lenses to systematically reduce myopia. It is considered to be a controversial procedure because of its questionable efficacy, safety, and the duration of its effects.

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History

Orthokeratology's beginnings date back to the 1950's and 1960's when eye care practitioners noticed that the keratometric readings (and thus presumably the corneal curvature) and the refractions of their contact lens patients changed over the years. Myopic patients tended to become less myopic with flatter corneas, but some became more myopic with steeper corneas.[1]

Orthokeratology (Ortho-K/OK) was originally defined as the "programmed application of contact lenses to correct refractive errors"[2] because orthokeratologists believed they could reduce all refractive errors by either flattening or steepening the cornea. The procedure usually consists of fitting a series of progressively flatter hard contact lenses to initiate a change in the corneal curvature.[3] Most practitioners found that steepening the cornea to reduce hyperopia caused significant corneal edema and distortion and abandoned work on hyperopes in favor of reducing myopia by flattening the central cornea. Some work with astigmatic reduction has been done using bitoric lenses with "axes crossed with respect to the corneal astigmatism." Prism ballast or truncation was used to hold the lens in the proper orientation.[4]

It is helpful to understand the kinds of myopia found in the population and which may be aided or influenced by the use of contact lenses. It is generally known that myopia can be caused by any, a combination of, or all of the following: raised refractive value of the lens, a steepened cornea, or axial extension.

Kemmetmuller[5] describes three main types of myopia:

1. *Scatter myopia* - is understood as a simple variation of the

morphological elements of the eye, never exceeding 4.00to 5.00D. It stabilizes at the age of 15 to 20 years.

2. *Benign-progressive myopia* - the degree of myopia may reach up to 12.00D, stabilizing by age 20 to 30 years. Usually there is no accompanying pathological changes to the fundus.

3. *Malignant-degenerative myopia* - is a pathological condition which has a genetic basis.

The first two types of myopia may be influenced by the use of contact lenses.[5]

Ziff[2] produced the first orthokeratology study in 1965 which attempted to determine if "emmetropization of the cornea can be predicted or accomplished partly or completely depending on the original existing degree of corneal curvature." Of the eight myopes studied, thirteen eyes flattened, the steeper eyes flattening most. One of the two relatively flat eyes steepened and the other remained the same. Other studies will be discussed later.

Techniques

The literature contains a wealth of information concerning fitting philosophies and fitting techniques with all reporting success. Perhaps one of the reasons that various fitting techniques can have similar effects is that K measurements can be variable. Further, the keratometer measures a very small portion of the central cornea (3 mm) and may not give reliable information between the comparison of the base curve of a contact lens and K measurements.

Jessen[4] used the contact lens as a "pressure bandage" to shape the

cornea. He used the lacrimal lake to compensate for the patient's myopia thus fitting a lens with a flat base curve which had to be large and thick for stability. He realized that a lens of these parameters would be uncomfortable but noted that it did reduce myopia.

Paige[6,7] used Jessen's flat lens but interchanged it with an alignment to .75D flat fit lens on alternate days. He called this lens his Plus Lens Increment(PLI) lens and the flatter lens the Orthokeratology lens. He felt that he could speed the orthokeratology process by alternating lenses and also equalize the response between the two eyes.

In the 1970's Fontana[8] used a lens that was less flat (slightly steeper) than the above orthokeratologists. His lens was a one piece lathe cut bifocal contact lens fit 1.00D flatter that the paracentral base curve. He reported in one of his studies that 96% of 50 patients experienced improved visual acuity and reduced myopia. A corneal flattening between .50 and 1.00D resulting from his program.

Ziff[9,10] fit myopes according to their keratometric measurements: he fit on K if the K's were flat (8-8.5mm); he fit 0.12D to 0.50D flat if K's ranged from 7.35-8.0 mm; and he fit 0.50D to 1.00D flat if the K's were steep (7.0-7.35 mm). Ziff used a 9.0 mm over-all-diameter (OAD) lens with 7.6 mm optic zone (OZ); the OAD and OZ were reduced by .1 mm for every 0.50D that the base curve was flattened. He suggested use of the lens fourteen hours each day with a special retainer lens for night wear. Some problems with corneal integrity, usually edema, sometimes resulted. He then switched to a fenestrated lens with smaller diameter which gave better success. Ziff found that myopia reduction was best accomplished in patients with low amounts of refractive error. 20/20 acuity was experienced in 100% of his patients with 1.25D of myopia or less and 55%

of myopes with -1.50D.[11]

Practitioners have found that excessively flat fitting contact lenses are not the only way to produce orthokeratologic effects. Neilson, May and Grant[12] used a series of lens fit 0.12D to 0.37D flatter than the flattest corneal meridian, changing the lens as the cornea molded to the procedure's effects. This fit produced significantly less corneal edema than the previously used flatter lenses.

Kemmetmuller[5] also fits his orthokeratology lens slightly flat making sure, he points out, that corneal metabolism is maintained. He changes the lenses based on data collected at regular 6-week check-ups and notes that measurable corneal changes continue to occur from 6 months to 2 years after initiation of orthokeratology.

He recommends the use of an aspheric lens because of its comfort, as the surface contact is greater. The optical zone diameter of his orthokeratology lens is 3 to 4 mm. The over all diameter is not critical to his fitting because the lens has parallel contact at the periphery independent of its size. The pressure the contact lens exerts is concentrated on a small narrow ring between the optical zone and the periphery usually not larger than 0.5 to 0.75 mm wide.

Jenkins[13] also found that a slightly steep fit may not result in the corneal distortion and edema often found with a flat, alignment, or very steep fitting lens. He reasoned that the keratometer measures the visual axis and not the anatomical axis which is located 15 degrees temporally to the visual axis. He points out that a slightly steep lens fits better (due to better centering) than an alignment or flat fit and that the decentration of the lens is usually the culprit in producing corneal distortion.[14] If orthokeratology could be effected with a slightly steep lens the adverse

effects of the procedure could be avoided. Tabb[15] found exactly that. His fitting method will be examined in detail later.

Freeman changed his orthokeratology lens from the early flat fitting lenses to one with a more aspheric peripheral curve and an alignment or slightly steep fit in the mid 1970's. With this lens he found that 80% of his myopic orthokeratology patients reduced their refractive errors by as much as 2.50D.[16]

Tabb[15] begins all his orthokeratology patients with an alignment or slight apical clearance fitted contact lens which he evaluates with the biomicroscope and corneascope. Three peripheral curves are used on his orthokeratology lens each 0.2 mm wide and cut one mm flatter than the preceding curve. Each curve is highly blended to simulate an aspheric periphery. The overall diameter is equal to the flattest keratometric reading or K_f + 1.00mm, with optical zone comprising 70% of that area leaving 30% to the peripheral curves and thus creating a 30% tear reservoir.

Tabb feels that the 30% tear reservoir is necessary for maintaining a balance between lens and corneal forces and to avoid stagnation of the tears under the lens. A tear reservoir less than 30% causes a poor tear exchange between fluid under the lens with that outside it. This causes poor oxygen transfer to the cornea, edema, and also creates forces which steepen the corneal curvature. As one might expect, a reservoir greater than 30% initiates inwardly directed forces applied uniformly across the cornea which flatten it. Gradually increasing the tear reservoir from 30% to 40%, Tabb can use a base curve steeper than K_f to produce orthokeratologic effects.

Reducing myopia by changing the optic zone of the contact lens causes it to center better compared to flat fitting orthokeratology lenses used by other practitioners. Tabb insists that his lens provides adequate tear exchange, does not cause corneal edema, and generates corneal flattening without mechanically abusing it.[15] Flatter lenses usually ride high and can induce an increase in with-the-rule astigmatism.[17-31]

Barr, et al., [32] in 1981 studied the effects to corneal thickness from hard contact lenses fit 1.00D flatter than the flattest corneal meridian (K_f), 0.50D flatter than K_f, fit on K, 0.50D steeper than K_f, and 1.00D steeper than K_f, all having the same overall diameter and optic zone. They found the flatter than K fitting to be the most desirable in that it caused the least amount of corneal thickening (see Table 1). The most corneal thickening was found with lenses fitted 1.00D steeper than K. This lens fit, as will be discussed later, is contraindicated for cosmetic or orthokeratology fitting because of its long term effects, namely inducing with-the-rule astigmatism [27].

Patient Selection

As early as 1970, Freeman[16] found that patients with corneas that were initially relatively spherical from center to periphery did not respond well to orthokeratology. Patients with steeper corneas centrally than peripherally showed the greatest myopia reduction from the procedure[27,33].

Binder explains that the patient population of his study showed that a successful orthokeratology patient would be one with a horizontal

meridian of the cornea steeper than the vertical meridian, i.e., having against-the-rule astigmatism. He also perports that myopes with refractive errors less than 3.75 diopters are better candidates than those with higher amounts of myopia and can expect to achieve four or five lines of improvement in uncorrected vision.

However, Kerns[34] stated that there is no indication as to which patients will respond from the pre-fit examination. He indicates that using this data, one cannot offer a solid prognosis of the procedure.

Mode of Orthokeratology

As discussed earlier, it was initially assumed that extremely flat contact lenses were the only lenses that could initiate a reduction of myopic refraction by flattening the central cornea and that very steep contact lenses steepened corneas, thereby accomplishing a reduction of hyperopic refraction.[4,13] The theory is that in the absence of edema, the cornea molded to the shape of the contact lens placed on it.

As orthokeratology techniques developed it was learned that extremely flat, slightly flat, alignment fit, and even slightly steep contact lenses all could effect orthokeratology by flattening the cornea. These lenses must have something in common because they all reduce myopia.

Watkins[35] suggests that mechanical pressure exerted on the cornea from the contact lens causes the flattening. He explains that orthokeratology lenses differ from cosmetic lenses in that they are all stiffer and no matter what the base curve-to-cornea relationship is, they tend to fit looser. This does not account for the fact that many cosmetic

contact lens wearers experience the effects of orthokeratology after a few years of wear.[17, 36-39]

Kemmetmuller[5] believes that orthokeratology is effected by the combined forces of a slightly flat fitting contact lens, those being: lens adhesion to the corneal surface, pressure of the eye lid, and pressure of the lens. He explains that these pressures cause no particular consequence when the lens is fit parallel with the cornea, but can potentially be dangerous if concentrated on a smaller surface of the cornea as in orthokeratology. To that end he suggests using an aspheric contact lens made of gas permeable material.

Kemmetmuller's discussion of histological changes produced from the use of orthokeratology is worthy of note. The theory finds its basis in examination of corneal sections obtained after keratoplasty surgery and of the eyes of post-mortum individuals who had used contact lenses. It was found that the corneal stroma is transformed to some extent through the use of contact lenses.

He describes a sterile, controlled keratitis being produced in the corneal stroma causing a concentration of inflamed cells in the area[5]. Phagocytes, which reduce the inflamed cells, then reduce the pressed tissues while regeneration is started at the epithelium first and is followed by regeneration of stromal tissues which are adapted to the new corneal shape. This regenerative mechanism is slightly modified and more complicated than simple regeneration. Migrating cells are developed and work actively with increased viability. Newly developed cells are described as long, larger, ramified cells similar to fibroblasts which function to replace tissue by minute fibrils in their cell bodies. The process is completed as the fibrils transform to fibroid tissue and the

migrating cells decrease in number.

Dickenson was one of the first practitioners to explain orthokeratologic effects, especially with small steep lenses, by the "hydraulic pressure of the eye fluids pressed against the cornea by the contact lens."[40] Tabb[15] agrees with Dickenson by saying that it is the pressure of the tear cushion beneath the lens distributed evenly over the corneal area which initiates orthokeratology.

Morrison[36] suggests that the cause of myopia has a metabolic component, that is, poor calcium metabolism may be a contributing factor to myopia. He feels that the mechanical massaging action, in addition to the role of hydraulic pressure, of a contact lens enhances the calcium metabolism in a positive way which in turn reduces the myopia. He further suggests that the continual pumping/flushing of oxygen under the lens with each blink increases the flow of oxygen to the ciliary muscle relieving any tendency toward ciliary spasm which may be adding to the myopic shift.

Many other practitioners[38, 41-43] agree with Morrison's feelings concerning the reduction of myopia through decreasing ciliary spasm. They also note that the use of contact lenses theoretically increase the accommodative demand, though in actuality may decrease it by providing less prismatic effects, a larger depth of focus and field of view, and less spherical aberration than does a spectacle correction. The reduction of accommodation which contact lenses may yield would be important only in reducing pseudomyopia and have no real factor in refractive error reduction in true myopia, Stoddard says.[44] He points out that pseudomyopia can account for only 0.75D to 1.00D which is but half the amount of some reported reductions from orthokeratology.

There are some orthokeratologists who suggest that the procedure may change other anatomical parameters than just the anterior corneal curvature. Nolan[45], Rengstorff[46], Ziff[47,48], and Garber[49] have considered that changes in anterior chamber depth and axial length may be contributing factors in myopia reduction in addition to the corneal flattening. Rengstorff[46] has theorized that "orthokeratology might also be accompanied by changes in the posterior corneal curvature, corneal thickness, posterior and/or anterior crystalline lens curvatures, and corneal metabolism as it is affected by lacrimation, turgescence, and deturgenscence."

Politzer[50] explains that the small amount in axial change which might result from corneal flattening would have very little effect on the refractive status of contact lens patients. Erickson and Thorn[51,52] calculate that the shallowing of the anterior chamber would decrease the refractive error by only 0.04D. They indicate that the combined effect of a change in corneal thickness and corneal index of refraction would maximally effect the refraction by a reduction of 0.12D.

Orthokeratology Studies

Orthokeratologic studies are difficult at best due to compounding factors affecting patient responsiveness. Human beings undergo a diurnal variation in refraction, keratometric measurements, and corneal topography.[53-57] Diurnal variations were found to be significant in contact lens wearers and most significant in patients who have worn lenses for many years. These variations tend to be somewhat predictable, but other factors such as emotional states, hormonal states and ambient

temperatures all effect corneal plasticity. It is known that the central cornea flattens when exposed to warm air and steepens in response to cold air, for example.[56]

Since so many fitting conditions seem to effect orthokeratology, procedural studies noting more than just keratometric changes are indicated; studies in which conditions are carefully monitored to minimize or control for diurnal fluctuations, temperature, emotional and hormonal states. Four controlled orthokeratology studies are found in the literature, each of which are discussed here.

Kerns' Study

This was the first controlled orthokeratology study which was performed at the University of Houston between 1976 and 1978.[22-27, 34, 58] It had two control groups: one consisted of three non-contact lens wearing individuals and one consisted of thirteen conventionally fit contact lens wearers. The experimental group contained eighteen individuals each of whom was fit with a modified May-Grant orthokeratology lens. Members of this group ranged from 10 to 30 years of age, had initial keratometric readings from 41.00D to 47.00D, less than 1.00D of corneal or refractive cylinder, and less than -3.50D (spherical equivalent) of refractive error.[22]

As mentioned, the contact lens control group wore alignment fit lenses while the experimental group wore lenses fit anywhere from an alignment fit to 0.50D flatter than the flattest corneal meridian (K_f) as measured with the keratometer. Lenses were fit progressively flatter as the refractions decreased in minus power or a flattening of the cornea was measured. As the corneas of this group became sphericalized, the lenses tended to decenter and ride high which caused distortion of the

keratometry mires, induced with-the-rule astigmatism, and increased spectacle blur. Compensatory fits included steepening the contact lens base curve or increasing its over-all-diameter. Seventy percent of the orthokeratology lenses were fitted flat, 13% fit on K_f, and 8% fit steep.[22-24]

Kerns used the following parameters to determine corneal response: unaided visual acuity, contact lens over refractions and post-wear refractions in both spherocylinder and spherical equivalent forms, corneal integrity, lens position and lag, central and peripheral corneal thickness using pachometry, keratometry, and PEK.

Results from Kerns' study showed that the two contact lens groups underwent changes that differed significantly from the non-contact lens wearers. Additionally, the orthokeratology group experienced changes which were statistically significant from the conventionally fit contact lens control group.[23-27, 58]

Kerns[25] found that the orthokeratology group had an improvement in visual acuity and the refractive error was reduced, particularly in the spherical equivalent refraction. Comparing the three groups, the spectacle control group showed a slight increase in myopia as a whole while both contact lens groups decreased in myopia, the orthokeratology group decreasing the most.

Kerns used Brungardt's[59, 60] methods to calculate the changes in corneal curvature. The methods showed that most orthokeratology occurred at the anterior corneal radius and that the changes took place within the first year of treatment. Some corneal distortion was in evidence, usually when the cornea became spherical, which caused the lens to decenter temporally and superiorly, or when the lens was fit more that

0.50D flat. The decentered lenses produced an increase in with-the-rule astigmatism and a fluctuation in visual acuity, corneal curvature, and refractive error.[23-25, 58]

Kerns stresses that the initial corneal shape factor measured with the PEK was more important in predicting the direction and magnitude of myopia reduction than the cornea to base curve relationship.[27] He found that if the shape factor was positive, myopia would continue to decrease until the shape factor reached zero, when further refractive error reduction was difficult to accomplish without adverse corneal reaction.

He also suggests that corneal rigidity, in addition to corneal shape factor, may be primary in effecting orthokeratology.[26] He noted that some corneas in his studies with similar parameters had basically the same treatment yet responded differently.

Binder's Study

The Binder study[61] compared 23 orthokeratology patients from May and Grant's practice to 16 cosmetically fit contact lens wearers from that practice. All patients were given the following tests prior to contact lens wear and every three months for two years: case history, visual acuity (unaided and with contacts), applanation tonometry, dilated fundus exams, biomicroscopy (including corneal endothelial checks), corneal sensitivity using the Cochet-Bonet anesthesiometer, PEK, axial length, anterior chamber depth, corneal thickness, keratometry, manifest and cycloplegic refraction, and contact lens verification.

The cosmetic contact lens control group wore the same pair of lenses for the length of the two year study while the orthokeratology group's lenses were changed every six weeks. He used the keratometric measurements and verified base curve of the old lens to determine the

parameters of the new lens.

Binder did not report any information of lens positioning, though it is likely that the orthokeratology lenses did not center as well as the cosmetic contact lenses did. This is inferred from the fact that the orthokeratology group experienced increases in with-the-rule astigmatism, which as mentioned earlier, is commonly caused by contact lens decentration. The experimental group showed an average increase of astigmatism of 0.50D while the control group actually decreased their with-the-rule astigmatism by 0.30D.

Binder's orthokeratology group had a much lower initial average refractive error (-2.50D) compared to the control group (-5.15D). This could have biased his findings since he and other practitioners have found that the higher the myopia the smaller the improvement in unaided visual acuity.[61]

At the start of his study, he classified his orthokeratology subjects into three categories by the amount of refractive error present, low myopia 1.87D ± 0.40D, moderate myopia 3.78D ± 1.20D, and high myopia 4.72D ± 0.64D. Binder later divided the same group into three different categories based upon their response to the procedure. The groupings appear in the accompanying table (Table 2). It is interesting to note that the "no response" group had the highest initial refractive error, the "variable" group had the lowest, and the "good" group's refractive error fell in between the above two.

Binder's results showed that the total orthokeratology group's acuity went from 20/120 to 20/40 in twenty-four months of the therapy. The majority of cases within the experimental group underwent improvements in vision between 11 and 18 months. If the vision had not improved by 18

months, it usually did not improve after that time (see Fig. 1).

Binder divided his experimental group into three for analytical purposes: group A having more than 2.50D of myopia and group B having less than 2.50D of myopia. Group C was a subset of group A which had more than 4.00D of myopia. He found no significant difference in the average visions of groups A and B suggesting that orthokeratology performed by Binder was effective in myopes with refractive errors less than -3.78 diopters (-3.78 diopters was the average refractive error of group A). The average vision in group C began at 20/400, progressed to 20/150 by 16.8 months, and finally to 20/100 by 25.2 months (see Table 3).

He found that the improvement in unaided visual acuity did not correlate well with keratometric changes, yet the control contact lens group had significant changes in keratometry measurements, but not significant changes in unaided visual acuity. He suggested that this might have resulted from corneal curvature changes that were not measured or from an increased vertical line discrimination which an increase in with-the-rule astigmatism might produce.

Freedman[62] might disagree with this reasoning. He feels that the corneal changes induced by orthokeratology do not occur at the central cornea but in the paracentral region in the area of the fourth to ninth corneascope rings. The keratometer measures the central cornea at the third corneascope ring and for this reason one would not expect keratometric changes to correlate well with refractive change.

Finally, Binder did not find any significant changes in corneal thickness (contrary to Kerns' findings), axial length, and anterior chamber depth.

Berkeley Study

The School of Optometry, University of California at Berkeley, produced a study which had two major objectives. First to evaluate the relative efficacy of orthokeratology by assessing changes in refractive error, visual acuity, and corneal curvature and secondly, to evaluate the safety of the procedure by assessing changes in corneal staining, corneal thickness, visual acuity, astigmatism, and endothelial cell density.

Subjects for the study were chosen using the following criteria: flattest corneal curvatures between 40.50 and 47.00D, corrected visual acuities of 20/20 or better in each eye, less than 0.75D astigmatism, less than 1.00D of anisometropia, and myopia between 1.00 and 4.00D. The subjects were also those who had never worn contact lenses, were free of ocular disease, were in good physical health, and not taking systemic drugs which have ocular side effects.

The eighty subjects chosen to participate in the study were randomly placed into treatment and control groups, forty in each. The two groups were remarkable similar, the baseline mean levels of the study characteristics were not substantially different between the two groups.(see Table 4) Of the eighty subjects initially chosen for the project, fifty-nine were involved to its conclusion. The data for these non-dropouts is also presented in the table.

PMMA (polymethyl methacrylate) or PMMA-silicone combination (Polycon) lenses were used in the study. All participants were initially fit with PMMA lenses and were re-fit with Polycon lenses when adverse physiological responses could not be controlled with PMMA lenses. The lenses fit on the treatment group differed from those fit on the control group in that they tended to be flatter, thicker, and had a larger overall

diameter.

The treatment plan consisted of three phases: the adaptive phase, post-adaptive phase, and a third phase when the subjects gradually decreased lens wear until discontinuation.

Dispensing initiated the beginning of the adaptive phase (Phase A), during which all patients were examined weekly until wearing time was up to 12 to 14 hours daily. During the adaptive phase lenses were re-fit only to correct adverse corneal responses, usually mild corneal edema.

The last examination of the adaptive phase began the post-adaptive phase (Phase B); subjects had monthly follow-up exams for the next year. During each monthly visit subjects received two examinations, one in the morning between 8 and 10 AM before putting their lenses on and again that same day after six to eight hours of wear. Members of the control group received new lenses only to counter adverse effects while treatment group's lenses were changed to induce corneal flattening.[63]

The last post-adaptive visit marked the beginning of Phase C of the study. This phase consisted of two portions: one in which the lenses were gradually withdrawn and one described as the postwearing segment. Subjects in both groups were told to decrease wearing time by one hour each day for four days and then to maintain this reduced wearing schedule until their next weekly examination. This routine was repeated until lens wear was discontinued. At that time bi-weekly exams were scheduled for the next two months or longer if more time was needed for corneal stability to be achieved. Stability was defined as the date at which no changes were noted within specified limits from the preceding examination. These limits were 0.25D of cylinder and sphere measured by subjective refraction and 0.50D of corneal curvature in both horizontal and

vertical meridians using keratometry. Any necessary visual correction during Phase C was provided for with spectacles.

Polse, et al. found a significant change in the mean equivalent sphere of 1.01D in the treatment group which was approximately twice the change in the control group (0.54D).[65] The mean change in corneal curvature was also significant comparing the two groups, but only the horizontal meridonial change was statistically significant. The changes in curvature were in the same direction of the refractive changes, but only about half as large. The visual acuity of -0.27 [log(MAR); MAR is minimum angle of resolution] experienced by the treatment group corresponds approximately to an improvement of three Snellen lines, this is one line less than would be expected from such a change in spherical equivalent.[65-67]

Figure 2 shows that 40% of the treatment group had an overall change in refractive error of 1.00D compared to only 18% of the control group. Further, 18% of treatment subjects experienced a 2.00D or greater change in spherical equivalent while none of the control group's subjects experienced like changes.[65]

He also found that 40% of treatment subjects had a twofold or greater improvement in unaided visual acuity [Δlog(MAR) = 0.3 or greater]. Only 25% of the control group showed this degree of improvement in acuity. Changes in vertical and horizontal corneal curvatures were found. About 40% of those in the treatment group had a reduction of corneal curvature, i.e. flattening, of 0.50D or more compared to 20% of the control group with like changes.[65]

The results of the Berkeley study show that orthokeratology can effect a reduction in myopia of 0.50D more on the average than conventionally fit contact lenses. The total refractive error change

resulting from the procedure is thus around 1.00D. This compares with the earlier studies. Kerns[27] found an overall change of 0.87D and Binder et al.[33] a 1.37D myopic reduction.

Members of the Berkeley study team consistently found keratometric measurements to be about 0.50D less than the change in refractive error changes. They, like earlier practitioners, suspect this is because the keratometer measures two central corneal points separated by 3 mm and that orthokeratologic effects occur more peripherally.

Polse et al. found that is was possible to reduce myopia in nearly all of their subjects, but that the reduction was largely temporary. Refractive error, visual acuity, and corneal curvature all tended toward the pre-treatment levels as lens wear was gradually decreased. Forty-five percent of the overall change in refractive error was lost during Phase C when lens wear was reduced to four hours per day.[65] This rebound effect, they suggest, indicates the high degree of corneal elasticity present in all individuals, no matter the magnitude of orthokeratologic change or baseline characteristics. A complete return to baseline levels did not occur even when contact lens wear was completely discontinued. The treatment group retained 26% of the overall change in subjective spherical equivalent indicating that the procedure has some permanent effects.[65]

This reversal to pre-fit levels shows that some form of retainer lens wear is needed if the therapeutic effect is to be maintained.[65]

The second portion of the Berkeley Study dealt with adverse side effects of orthokeratology. Ocular parameters studied included: corneal thickness, endothelial cell density, refractive astigmatism, corneal toricity, correctable spectacle acuity, and corneal edema and staining.

Pachometry was used to assess changes is corneal thickness which largely was due to corneal hydration. Investigating corneal thickness gives an indirect evaluation of metabolic disturbances to the cornea that might be caused by contact lens wear. Since there is some indication that endothelial cell function is altered in soft contact lens wearers, endothelial cell counts were taken during this study, because the fitting technique used by the study team causes corneal bearing. Refractive astigmatism was measured with subjective refractions and corneal toricity with keratometric measurements. Spectacle blur was measured with appropriate spectacle lenses placed in a trial frame after subjective refraction; measurements were expressed in logarithm of the minimum angle of resolution [log (MAR)], i.e. the log of the reciprocal of the Snellen fraction. Corneal edema and staining were evaluated using the slit lamp and graded on a 0 to 3 scale, where 0 indicated the absence of the condition and 1, 2, and 3 indicated light, moderate, and marked, respectively.[57]

Changes in the safety parameters were generally small and insignificant. (see Table 5) Corneal thickness decreased by 0.2µm and 3.2µm in the treatment and control groups respectively. Changes in refractive astigmatism were less than 0.10D in both groups. Visual acuity changes amounted to less than one Snellen line. Endothelial cell densities actually increased by 257 cells/mm^2 in the treatment group and 143 cells/mm^2 in the control group.[57]

Tables 6 and 7 present data on the distribution of corneal staining and edema evaluated with slit lamp examination at the AM and PM follow-up examination during Phase B of the study. As shown, the amounts of edema and staining were slight and within clinically acceptable levels and that

little difference is present between treatment and control groups. There was slightly more corneal edema observable comparing the AM and PM examinations in both groups. As might be expected, the frequency of limbal staining after 6 to 8 hours of lens wear was higher than at the pre-wear examination with about 60% of both groups showing grade 1 staining. Overall the difference between responses of the subjects wearing orthokeratology lenses and responses of those fit with conventional lenses were small, and the grades of edema and staining observed were not clinically significant.[57]

Pacific University Study

The Pacific University Study was done from 1976 to 1979 with the purpose of learning if myopia could be reduced, using alignment to slightly steep contact lenses, without inducing with-the-rule astigmatism. The investigation began with a pilot study in which fifteen patients were randomly place into three equal groups: a spectacle control group, a contact lens control group, and an experimental group to which orthokeratology lenses were fit.[68] A secondary longitudinal study added 10 patients to the contact lens control group and 19 patients to the experimental group; the spectacle control group was discontinued.

Both control and experimental subjects were free of ocular pathology, had little or no previous contact lens wear, showed myopia between 1.00D and 3.00D, and had flattest keratometric measurements between 41.00D and 46.00D. Examination of the baseline data showed an even match between the control and experimental groups.

Ocular parameters measured routinely were unaided and aided visual acuity, refraction with and without contacts, contact lens fit, ocular anterior segment health, anterior corneal curvature, corneal shape factor,

central and peripheral corneal thickness, anterior chamber depth, vitreous depth, axial length, anterior and posterior crystalline lens curvatures and powers, crystalline lens thickness, and intraocular pressure.

Biomicroscopy examinations included checks for corneal edema, fluorescein retention, perilimbal injection, and tear break-up time.

The fitting procedure used was that of Tabb, mentioned earlier. All patients were initially fit with PMMA contact lenses with an aspheric periphery. The contact lens control group was initially fit with lenses having a 30% tear reservoir while the experimental group was fit with lenses having a 32.5% reservoir. The fit of the control group's lenses were not changed during the study, but the tear reservoir of the orthokeratology group was purposefully, incrementally increased to 35%, 37.5%, 40%, 42.5%, and 45% while keeping the lens diameter and base curve constant.[68] Changing the tear reservoir was indicated when the unaided visual acuity stabilized after two patient visits.

Statistically significant changes occurring in the experimental group included unaided decimal visual acuity, refraction, corneal topography, and corneal thickness. No significant changes were noted in anterior chamber depth, crystalline lens power, curvature or thickness, axial length, tonometry, or anterior segment health.

The orthokeratology group experienced an average 195% increase in unaided visual acuity which corresponds to an improvement of five and one half lines on a Snellen chart. The contact lens control also showed some improvement, but not to the same extent. The average increase for this group was 82% or three Snellen lines. The actual maximum myopia reduction resulting from the procedure was 0.96D @180 in the control group and 1.30D in the same meridian in the experimental group.

Corneal curvature changes were measured with the keratometer and PEK, the keratometric findings were more variable than PEK findings. Both contact lens groups showed an initial steepening of the central cornea followed by flattening. At week 80, the control group showed PEK flattening of 0.53D @ 180 and 0.25 to 0.37D @ 90 while the OK group only had 0.37D @ 180 and 0.25 to 0.37 D @ 90. It is interesting to note that only the control group had significant corneal curvature changes when comparing baseline and final PEK data. This seems inconsistent with the predominant theory that orthokeratology is effected by corneal flattening. Coon suggests that perhaps corneal topography is a better predictor of the amount of orthokeratology.

Both contact lens groups exhibited significant changes in corneal topography, the corneas studied became less aspheric over time with shape factors approaching zero (a zero shape factor describes a circle). The shape factor of the orthokeratology and control groups significantly decreased in both the 180th and 90th meridians. Coon believes that central corneal thinning combined with peripheral corneal thickening may alter the corneal shape factor toward sphericalization which explains the improvement in unaided visual acuity in OK subjects.

Pachometry data do not show significant changes of central corneal thickness in either contact lens groups. Ultrasound data do, however, point to central thickening in the control group and significant central corneal thinning in the orthokeratology group.

Complications

Minimal corneal distortion has been reported by many practitioners

resulting from orthokeratology[3,33,57]. No occurrence of corneal scars, endothelial damage, or corneal abrasions have been reported, though Levy[3] points to these potential results from the procedure.

Binder reported some of the patients from his experimental group had difficulty reading with their lenses; reading glasses were prescribed.

Quality of vision is a frequent complaint of orthokeratology patients. Some comment that the unaided quality of vision is less than that of a refraction or contact lens that gives equal acuity. They describe their vision as variable and irregular, sometimes like looking through a dirty window or through a fish bowl.

As mentioned here previously, an increase in with-the-rule astigmatism is not an uncommon occurrence in orthokeratology patients.[6, 18-27, 34, 58, 63, 69-71] This is usually induced from lenses that decenter.

Table 8 shows the percentage of complications in both treatment and control groups of the Berkeley study by reason for complaint. By far, the most frequent cause of problems was altered physiology. It is interesting to note the total numbers of complications between the groups, there were 76 individual cases of complications noted in the treatment group and 56 in the control group.

Conclusion

The incompleteness of reports and disagreement among professionals as to the efficacy, safety, and duration of effects of orthokeratology have caused considerable doubt and controversy regarding the procedure. The studies described here have done much to clarify the issues, but there is

much inconsistency between reporters.

The range of myopic reduction is widespread depending upon the reporting practitioner, anywhere from 1.00 diopter to 5.00 diopters of refractive error reduction can be found in the literature.

The Berkeley team concludes that:

1. It is possible to reduce myopia an average of about 1.00D by wearing appropriately fitted contact lenses.

2. The change is not permanent and would require some form of contact lens wearing regimen to maintain the therapeutic effect.

3. Vision when contact lenses are not worn is variable and can fluctuate from day to day making it difficult to predict the level of vision during periods of no contact lens wear.

4. Methods for maintaining stable vision during the period of lens wear need to be developed before OK will be a clinically appealing therapeutic treatment for myopia.

The observations of the Pacific University Study suggest that orthokeratology is as safe and effective as fitting cosmetic PMMA contact lenses. No more complications were incurred in the treatment OK group than the contact lens control group.

Binder[33] mentions in his study that the only consistent feature in the results of his orthokeratology group was the "high degree of variability and unpredictability of the results." He points out that he found no relationship between refractive error and visual acuity in his study patients. It is obvious from Binder's remarks that much investigation remains to be done before orthokeratology will be an accepted, viable option to myopia therapy.

	Treatment Groups					*Control*
	1 D FTK	0.50 FTK	On K	0.50 D STK	1 D STK	
Day 1 (4hr)	1.83	3.56	3.86	2.72	5.16	-0.46
Day 8 (6hr)	1.63	4.68	4.89	2.87	3.89	-0.19
Day 14 (8 hr)	1.21	3.66	3.07	2.85	4.15	-1.08

Table 1 - Average percentage of Corneal thickness change for treatment and control groups (days 1, 8, and 14.)

Barr, JT., Schoessler, JP.: "Flatter than 'K,' Steeper than 'K,': Does the Cornea Know the Difference." American J of Opt & Phys Optics 58:6-10, 1981.

	No Response (10 eyes)		*Variable (12 eyes)*		*Good Response (18 eyes)*	
	Prefit	Last	Prefit	Last	Prefit	Last
Unaided visual acuity	6/60	6/30	6/35	6/15	6/30	6/7.5
Spherical equivalent	3.95	3.27	1.98	1.74	2.03	1
Central horizontal curvature	43.3	42.81	43.35	42.89	43.47	42.57
Central vertical curvature	43.82	44.09	43.73	43.68	43.62	43.4
Follow-up	24 mo.		18 mo.		24 mo.	

Table 2 - Orthokeratology Subgroup Responses. Last = before retainer removal.

Binder, PS., May, CH., Grant, SC.: "An Evaluation of Orthokeratology."
Am Academy of Ophthal 87:729-745, 1980.

	Group A Greater than 2.50 diopters	*Group B* Less than 2.50 diopters	*Group C* Greater than 4.00 diopters
Number of eyes	11	25	5
Initial refraction	-3.78 ± 1.02	-1.87 ±0.40	-4.72 ±0.62
Best refraction	-1.86 ±1.71	-0.40 ± 0.89	-3.20 ± 0.54
Final refraction	-2.26 ± 1.60	-1.57 ±1.04	-3.27 ± 0.49
Initial visual acuity	20/286	20/100	20/400
Best attained visual a	20/45	20/26	20/150
Final visual acuity	20/45	20/30	20/100

Table 3 - Effect of Refractive Error on Final Vision and Refraction

Binder, PS., May, CH., Grant, SC.: "An Evaluation of Orthokeratology." Am Academy of Ophthal 87:729-745, 1980.

	Group Means		*Standard Deviation*	
	Treatment	Control	Treatment	Control
Objective spherical equivalent	-2.73	-2.7	1.25	1.21
Subjective spherical equivalent	-2.72	-2.6	1.16	1.12
Subjective cylinder	-0.48	-0.54	0.27	0.3
Keratometry				
horizontal	43.6	43.15	1.38	1.58
vertical	44.03	43.98	1.54	1.68
Age in years	26	26.2	4.01	4.97
Corneal thickness (mm)	0.543	0.544	0.028	0.02
Endothelial cell count per sq. mm	2224	2206	481	610

Table 4 - Baseline characteristics of randomized treatment and control groups.

Polse, KA., Brand, RJ.: "Contact Lens Effects on Ametropia: A Current Example of of the Clinical Trial." American J of Opt. & Phys Optics 58:281-288, 1981.

	Mean change		*Standard deviation*	
	Treatment	Control	Treatment	Control
Corneal thickness (mm)	-0.0002	-0.0032	0.015	0.011
Corneal astigmatism (D)	0.07	0.01	0.38	0.25
Spectacle visual acuity [log(MAR)]	0.02	0.018	0.019	0.01
Endothelial cell increase (cells/sq. mm	257.6	143.8	264.4	238.9

Table 5 - Changes in safety characteristics from baseline to final postadaptive visit.

Polse, KA., Brand, RJ., et al.: "The Berkeley Orthokeratology Study, Part III: Safety." American J of Opt & Phys Optics 60:321-329, 1983.

	Edema (%)		*Central Staining (%)*		*Limbal Staining (%)*	
Grade	Treatment	Control	Treatment	Control	Treatment	Control
0	87.5	92.2	73.3	77.9	52.3	58.1
1	12.5	7.8	26.6	22.1	47.7	41.9
2	-	-	0.2	-	-	-
Total	100	100	100	100	100	100

Table 6 - Percentage distribution of grades of corneal edema and staining assessed by slitlamp at AM examinations during Phase B of the study.

Polse, KA., Brand, RJ, et al.: "The Berkeley Orthokeratology Study, Part III: Safety." American J of Opt. & Phys Optics 60:321-329, 1983.

	Edema (%)		*Central Staining (%)*		*Limbal Staining (%)*	
Grade	Treatment	Control	Treatment	Control	Treatment	Control
0	13.7	16.1	78	81.3	40.6	40.1
1	81.6	80	22	18.7	59.4	59.9
2	4.6	3.8	-	-	-	-
3	-	0.2	-	-	-	-
Total	100	100	100	100	100	100

Table 7 - Percentage distribution of grades of corneal edema and staining assessed by slitlamp at PM examinations during Phase B of the study.

Polse, KA., Brand, RJ, et al.: "The Berkeley Orthokeratology Study, Part III: Safety." American J of Opt. & Phys Optics 60:321-329, 1983.

Reason for visit:	Percent in treatment group	Percent in control group
Altered Physiology	38	39
Comfort	22	22.5
Visual Acuity: patient initiated	19.5	19.5
Handling of Lenses	8	6
Visual Acuity: examiner initiated	6	6
Lens Performance/Handling	2	7
Miscellaneous	5	2

Table 8 - Percentage distribution of reasons for 76 complication visits.

Polse, KA., Brand, RJ., et al.: "The Berkeley Orthokeratology Study, Part III: Safety." Am J of Opt & Physiol Opt 60:321-329, 1983.

FIGURE 1

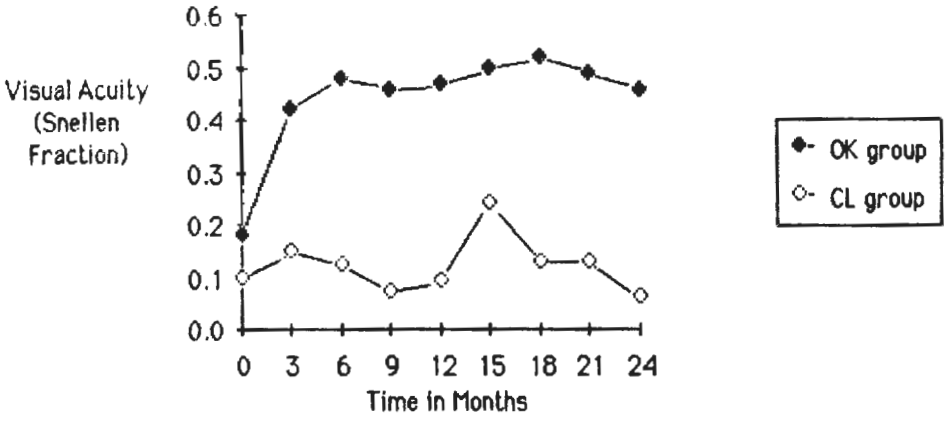

FIG. 1 - Average visual acuities between contact lens (CL) and orthokeratology (OK) groups. Note the decline in visual acuity beginning at the 18 month follow-up visit; this is when the retainer lenses were removed. (see ref. * 33)

FIGURE 2

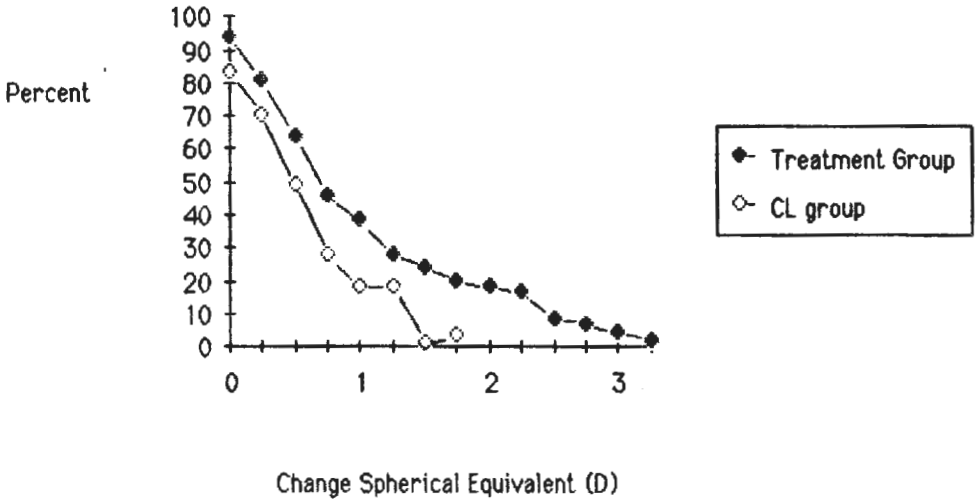

FIG 2 - Percentage of treatment and control subjects showing spherical equivalent change. (see ref. * 65)

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